

## (12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property  
Organization  
International Bureau



(43) International Publication Date  
31 July 2003 (31.07.2003)

PCT

(10) International Publication Number  
**WO 2003/062401 A3**

(51) International Patent Classification<sup>7</sup>: **C12N 15/00,**  
5/00, C07H 21/00

(21) International Application Number:  
PCT/US2003/002353

(22) International Filing Date: 22 January 2003 (22.01.2003)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:  
10/057,475 22 January 2002 (22.01.2002) US

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(81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH,

GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

#### Declarations under Rule 4.17:

- as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii)) for the following designations AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA, ZM, ZW, ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG)
- as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii)) for all designations
- of inventorship (Rule 4.17(iv)) for US only

#### Published:

- with international search report

(88) Date of publication of the international search report:  
26 February 2004

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: COMPOSITIONS AND METHODS FOR THE DETECTION, DIAGNOSIS AND THERAPY OF HEMATOLOGICAL MALIGNANCIES

(57) Abstract: Disclosed are methods and compositions for the detection, diagnosis, prognosis, and therapy of hematological malignancies, and in particular, B cell leukemias, lymphomas and multiple myelomas. Disclosed are compositions, methods and kits for eliciting immune and T cell responses to specific malignancy-related antigenic polypeptides and antigenic polypeptide fragments thereof in an animal. Also disclosed are compositions and methods for use in the identification of cells and biological samples containing one or more hematological malignancy-related compositions, and methods for the detection and diagnosis of such diseases and affected cell types. Also disclosed are diagnostic and therapeutic kits, as well as methods for the diagnosis, therapy and/or prevention of a variety of leukemias and lymphomas.

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WO 2003/062401 A3

# INTERNATIONAL SEARCH REPORT

International application No.

PCT/US03/02353

| <b>A. CLASSIFICATION OF SUBJECT MATTER</b><br>IPC(7) : C12N 15/00, 5/00; C07H 21/00<br>US CL : 536/23.1; 435/325, 320.1<br>According to International Patent Classification (IPC) or to both national classification and IPC  |  |                       |
|---|--|-----------------------|
| <b>B. FIELDS SEARCHED</b><br>Minimum documentation searched (classification system followed by classification symbols)<br>U.S. : 536/23.1; 435/325, 320.1<br><br>Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched<br><br>Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)<br>Genbank |  |                       |
| <b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>   |  |                       |
| Category *  | Citation of document, with indication, where appropriate, of the relevant passages   | Relevant to claim No. |
| X   | Database Genbank on NCBI, US National Library of Medicine, (Bethesda, MD, USA), No. AB027233, FUJII, Y. 'Homo sapiens mRNA for membrane protein FOAP-12' 21 June 2001, see entire sequence.  | 1-3                   |
| <input type="checkbox"/> Further documents are listed in the continuation of Box C. <input type="checkbox"/> See patent family annex.   |  |                       |
| * Special categories of cited documents:  |  |                       |
| "A" document defining the general state of the art which is not considered to be of particular relevance  | "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention  |                       |
| "E" earlier application or patent published on or after the international filing date   | "X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone   |                       |
| "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)   | "Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art |                       |
| "O" document referring to an oral disclosure, use, exhibition or other means  | "&" document member of the same patent family  |                       |
| "P" document published prior to the international filing date but later than the priority date claimed  |  |                       |
| Date of the actual completion of the international search   | Date of mailing of the international search report   |                       |
| 17 October 2003 (17.10.2003)  | 12 NOV 2003  |                       |
| Name and mailing address of the ISA/US  | Authorized officer   |                       |
| Mail Stop PCT, Attn: ISA/US<br>Commissioner for Patents<br>P.O. Box 1450<br>Alexandria, Virginia 22313-1450   | Lori A. Clow   |                       |
| Facsimile No. (703)305-3230   | Telephone No. 703-308-0916   |                       |

# INTERNATIONAL SEARCH REPORT

International application No.

PCT/US03/02353

## Box I Observations where certain claims were found unsearchable (Continuation of Item 1 of first sheet)

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claim Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claim Nos.:  
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claim Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box II Observations where unity of invention is lacking (Continuation of Item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:  
Please See Continuation Sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.: 1-3 and SEQ ID NO: 1

Remark on Protest

☐  
☐

The additional search fees were accompanied by the applicant's protest.

No protest accompanied the payment of additional search fees.

# INTERNATIONAL SEARCH REPORT

PCT/US03/02353

## BOX II. OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING

Groups 1-85: Isolated Nucleic Acids, Vectors: Group 1 = Seq ID No 1 and claims 1-3; Group 2 = Seq ID No 2 and claims 1-3. etc...

This logic follows for the rest of the groups.

Groups 86-122: Isolated Polypeptides: Group 86 = Seq ID No 4 and claim 9; Group 87 = Seq ID No 6 and claim 9. etc.

Groups 123-244: Antibodies/Immunoconjugates: Group 123 = Seq ID No. 1 and claims 4, 5, 10-13. etc.

Groups 245-330: Medicament using Polynucleotides: Group 245 = Seq ID No 1 and claims 6-8. etc.

Groups 331-367: Medicament using Polypeptides: Group 331 = Seq ID No 4 and claims 14-16. etc.

The inventions listed as Groups 1-367 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The inventions listed as Groups 1-367 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Each of the sequences of SEQ ID NOS 1-121 and 124 are separate and distinct polynucleotides or polypeptides having differing sequences, structures, and biochemical activities. As such, no single sequence is a shared special technical feature across all the Groups.

Please note that the examiner has interpreted claim number 1 to read: An isolated polynucleotide as set forth in SEQ ID NO:1 wherein said polynucleotide encodes a polypeptide or an immunogenic fragment thereof.